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10/582,372

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EXAMINER

CHAWLA, JYOTI

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,372	Applicant(s) FERGUSON ET AL.	
	Examiner JYOTI CHAWLA	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-19 are pending and examined in the application.

Specification

The attempt to incorporate subject matter into this application by reference to WO 99/37673 and WO 01/83534 as stated on page 5, line 18 of the original disclosure is ineffective because it excludes the root words "incorporate" and/or "reference" have been omitted, See 37 CFR 1.57(b)(1); the reference document is not clearly identified *as required by 37 CFR 1.57(b)(2)*.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective.

Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Claim Objections

Claim 1 is objected to because of the following informalities: In line 4, the phrase "which frozen confections" is suggested to be --wherein the frozen confections-- in order to indicate the limitations on the frozen confections. Appropriate correction is required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(A) Claims 1-13, 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenn et al (US 2001/0048962) in view of Jones (WO 96/29896).

Regarding claims 1 and 4, Fenn et al., hereinafter Fenn, teaches a method of making frozen food product, such as, water ices, sherbet, sorbet, ice milk, etc (Publication paragraphs [0050] and [0045, lines 2-3]) comprising discrete elements of the water ice containing ice structuring protein (ISP) or antifreeze peptide (AFP) (Publication

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paragraphs [0052]). Fenn teaches that the level of solids more than 4% and preferably more than 30%, and up to 70% (Publication [0051]), which includes the solids content of at least 15% by weight, as instantly claimed.

The reference also teaches that ISP/AFP acts in many ways to modify the frozen food product

- AFP lowers the freezing temperature of the solution (Publication [0005]).
- AFP has significant ice-recrystallization inhibition properties, i.e., ice crystal growth suppression (Publication [0006]), i.e., agitation is not required to make a smooth frozen product.
- AFP has the ability to influence the shape of ice crystals (Publication [0007]).
- AFP also inhibits the activity of ice nucleating substances (Publication [0008]).

The reference also teaches that ISP/AFP makes it possible to formulate frozen food products (ice-creams and water ices) that are relatively hard and brittle on one hand with improved ice-recrystallization properties on the other, i.e., the water ice or ice cream can be frozen in a static freezer. Since the AFP/ISP retards the growth of ice crystals, it would also retard the adjacent frozen confections or confection pieces to stick to one another as instantly claimed. Further ISP/AFP helps in retaining the desirable shape or size of the frozen food product and the ice crystals in the food would not increase in size significantly and thus there is no deterioration in the texture of the frozen food product upon keeping.

Fenn teaches that when ISP/AFP is added to the food product then the average ice crystal size of less than 20 μm , and preferably from 5 to 15 μm (Publication [0039]) which makes the size of the ice crystal such that the frozen product remains fluid and that the AFP/ISP used is the one that has good ice-recrystallization properties. The reference teaches of frozen confections such as water ices and sherbert or sorbet as discussed above. Fenn also teaches of ice-cream or water-ice mixes containing ISP/AFP, wherein the mixes are packaged for single and multiple portions. For single portions, the pack size as taught by Fenn varies from 10-1000 grams, i.e., packages having the volume of confection in the recited range of 5-100 ml were known and

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taught by Fenn. The reference does not specifically teach “an average volume” of frozen confection as instantly claimed. However, freezing ice confections in sizes and average volumes as claimed instantly have been known in the art. Jones teaches of making ice confections in the shape of small beads. Jones teaches of frozen confection spheres or beads that are free flowing when frozen. The frozen confection as taught by Jones can be made using a dropper assembly with orifice of size 0.03125 inches, i.e., 0.8 mm and the droplets of the confection are frozen quickly so as to form beads or spheres of frozen confection. Based on the viscosity of the liquid confection, the beads of the frozen confection formed can be made smaller or larger, however, it was known to make discrete ice confections at the time of the invention as taught by Jones.

Regarding the size of the frozen confection pieces or particles or spheres as recited in claims 1 and 4, it is noted that since the composition of the ice confection with solids content in the range claimed was known (Fenn), the confection composition also included the same type of ISP /AFP in the recited amount was also known at the time of the invention, therefore, the step of freezing the ice confection as to form a discrete pieces of the frozen confection of “an average volume” does not provide patentable distinction to the claims, absent any clear and convincing evidence and arguments to the contrary.

Regarding claims 2-3, Fenn teaches of a frozen food product comprising of ISP /AFP. The reference also teaches frozen confections that have texture contrast. The frozen confections taught by Fenn also teach discrete elements in the confection, e.g., core of one ice confection can be coated with composition containing ISP/AFP to create layered confection (Publication [0052-0064]), i.e., two or more discrete frozen confections. Thus, the reference does teach of discrete ice cream or milk-ice confections that contact other iced confections, as instantly claimed.

Regarding claim 5, Fenn teaches that the aeration of the frozen product is optional (Publication [0041-0042]). Thus, Fenn teaches that the frozen ice confections

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comprising ISP/AFP can be made without aeration step, i.e., unaerated water-ice, ice cream or milk ice, as is instantly claimed.

Regarding claim 6, Fenn teaches that the level of solids more than 4 wt% and up to 70% (Publication [0051]), which includes the solids content of at least 6 weight %, as instantly claimed.

Regarding claim 7, Fenn teaches of ice-cream or water ices that can optionally be aerated (Publication [0041-0042]). Thus, Fenn teaches that the frozen ice confections comprising ISP/AFP can be made with the aeration step, i.e., aerated ice cream or milk ice, as is instantly claimed.

Regarding claim 8, Fenn teaches that the level of solids in the frozen confections, ice-creams with more than 4 wt% and up to 70% (Publication [0051]), which includes the solids content of at least 15 wt %, as instantly claimed.

Regarding claim 9, Fenn teaches of butter-oil in an ice cream composition in the amount of 8% by weight of the composition (Publication [0053], Table), which falls within applicant's recited range of 2-15% fat for ice cream product.

Regarding claims 10-11, Fenn teaches that the preferred ISP/AFP is derived from type III fish and most preferred HPLC-12 (Publication [0038]), as is instantly claimed.

Regarding claim 12, Fenn teaches that the preferred level of ISP/ AFP in the frozen confections, such as ice creams and water ice is in the range of 0.0001 to 0.5wt% (Publication [0045]), which includes the range of at least 0.0005wt%, as instantly claimed.

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Regarding claim 13, Fenn teaches of frozen confections comprising ISP/AFP, where aspect ratio of the crystals is such that a frozen confection can be made brittle at a layer thickness that is less than what is required for traditional frozen confections (Publication paragraphs [0022-0033] and [0065-0069]). Regarding the minimum thickness required to obtain a brittle frozen confection Fenn teaches that the minimum layer thickness is less than 10mm [0025]. However, Fenn teaches that the aspect ratio of the ice crystals can be changed as it is influenced by factors, such as, rate of freezing, temperature of freezing, storage temperature, storage time, mobility of product during freezing, presence and amounts of certain ingredients (gums, fats etc.), nature and amount of ISP /AFP present in the confections (Publication, paragraphs [0026-0031]). Fenn also teaches that a skilled artisan would be able to choose conditions to obtain desired aspect ratio of ice-crystals [0026]. Fenn does not specify the thickness of the frozen confection, however, Fenn teaches of several embodiments where frozen confections can be made, where the frozen confections comprise of alternating layers of ice-cream with hard and crispy frozen confections [0052], i.e., a layered frozen confection where brittle layer is alternated with ice-cream layers and based on the discussion above a brittle layer is less than 10 mm and thickness of ice cream layers has not been disclosed. Further, ice-creams or frozen water-ice confections of various thicknesses and shapes and sizes were known in the art at the time of the invention. Therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to modify the shape or size or thickness of the frozen confection at least based on one or more of the parameters including the rate of freezing, temperature of freezing, storage temperature, storage time, mobility of product during freezing, presence and amounts of certain ingredients (gums, fats etc.), nature and amount of ISP /AFP present in the confections (Fenn Publication, paragraphs [0026-0031]), and availability and cost of specific shaped molds for freezing the confections, in order to obtain a desired aspect ratio of the crystals and a desirable thickness of the frozen confection in the range as claimed.

Further, regarding the thickness of the frozen confections comprising ISP/AFP, claim 13 recites "a minimum thickness of 10mm", however, the criticality of the thickness has not

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been shown. Applicant's disclosure clarifies the criteria for thickness by stating that "a minimum thickness of at least 10mm, i.e., they are not thin" (Page 2, lines 11-13, and Page 8, lines 21-22). Also, it has been held that where the general conditions of the claims are disclosed in the prior art, it is not inventive to discover the optimum or workable range by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 15, 17-18 Fenn teaches a frozen confection comprising a closed container. Fenn teaches of cartons, bags, boxes and plastic containers as examples of containers (Publication [0044]). Regarding the recitation of sealing means, Fenn teaches of closed containers for iced or frozen confections and mixes that can either be powder mix or liquid mix (Publication, [0041-0042]), which will be packed in a closable or sealable container for storing and/or shipping and/or freezing purposes, such as, a sealable bag or box or sachet, as recited in claims 15, 17-18. Therefore, it would have been obvious to one of ordinary skill in the art that the containers as taught by Fenn are sealable/closable containers, absent any clear and convincing arguments and evidence to the contrary.

Regarding the volume of the container as recited in claim 16, Fenn teaches that the pack size is from 10g to 5000g for single or multiple portions (Publication [0044]), which includes applicant's recited volume range.

Regarding claim 19, Fenn teaches of packing the frozen confection mix in individual sized or multi-portion containers or packs, i.e., multiple packs or plurality of containers (Publication [0044]) and that the frozen confection can be made and frozen in a shop or home freezer (Publication [0043]), where the frozen confection shop or the shelf in a shop that sells the frozen confection would comprise the retail unit. Regarding the limitation of product in each pack being different as recited in claim 19, Fenn teaches of frozen confectionery products, including ice-cream, frozen yogurt, sherbet, sorbet, ice-milk, frozen custard, water-ice, granitas, and frozen fruit purees (Publication [0050]).

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Therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to package various products in one package to be sold to a retail outlet. Further, it would also have been obvious to one of ordinary skill in the art at the time of the invention that each container filled with frozen confection, where the confection comprises of discrete water ice confections (particles, spheres etc) will have different product in each container at least due to the differences in the number of discrete frozen confections in a package, the flavor(s) of frozen confection the size of the packaging container, the shape of the packaging container, the packaging conditions and the type of product in the package etc., as instantly claimed absent any clear and convincing evidence and arguments to the contrary.

Therefore, claims 1-13, 15-19 are obvious over Fenn in view of Jones.

(B) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fenn in view of Jones, as applied to claim 1 above, further in view of the combination of Tucker et al (US 6099874) and York (US 2074500).

Fenn in view of Jones have been applied for the rejection of claims 1-13, 15-19 above. Fenn teaches frozen confections with ISP/AFP, as discussed above regarding claim 1. Fenn teaches of packaging the frozen confection mix in containers, but is silent regarding the frozen confection having a stick. Frozen confections with stick were known in the art at the time of the invention, e.g., Tucker et al, hereinafter Tucker, teaches of frozen confection with a stick (figures 1-5). Also molds for frozen confection wherein the confection is frozen with a stick were known in the art at the time the invention was made (York, figures 1-3). Therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to modify Fenn and freeze the confection in such a way that the frozen confection has a stick feature, at least for the reason of making the frozen product portable and easy to hold while consuming. Therefore, claim 14 is obvious over Fenn in view of Jones, further in view of combination of Tucker and York.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Note: Applications 10/582,278 and 10/582,372 have 3 inventors in common.

Claims 1, 3, 6, 8-12 of the current application 10/582,372 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-10 of copending Application No. 10/582,278. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim frozen confectionery comprising plurality of discrete frozen confections and each discrete frozen confection being able to contact directly other discrete frozen confections in the product. The frozen confections comprise an ice structuring protein (ISP) and have an average volume of less than 1 ml. The frozen confections comprise at least 0.0005 wt % of ISP and 2-15% fat in ice cream compositions. Claims in both applications also recite that the ISP is a fish type III ISP, which is a type III AFP HPLC 12. The overlapping claims differ in the minimal amount of

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solids in the frozen confection. Claim 6 of copending application 10/582,278 claims "at least about 15 wt% solids" whereas, claim 6 of current application 10/582,372 claims "at least about 6 wt% solids".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794